

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/594,839

06/15/00

ANTHONY

J

2629-4017

MORGAN & FINNEGAN LLP  
345 PARK AVENUE  
NEW YORK NY 10154

HM12/1010

EXAMINER

CHUNDURU, S

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

**Application No.**

09/594,839

**Applicant(s)**

ANTHONY ET AL.

**Examiner**

Suryaprabha Chunduru

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Applicants' response to Restriction Requirement (Paper No.10) filed on August 23, 2001 has been entered.

2. Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that claims are restricted by mischaracterizing the invention. This is found persuasive in part. In view of Applicants' arguments restricted Groups I, II and IV stand moot and the claims in these groups are rejoined herein and examined as claims under a single Group. Claims in Group III are drawn to a product classified in a separate class, subclass and restriction makes it clear that additional search would be required to examine Group III. Review of these additional search is prima facie evidence of burden which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-46 and 48-55 are considered for examination in this office action. Claim 47 is withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 19, 21-22, 40, 42, 48, 50-51, 55 and dependent claims 3, 4-18, 20, 23-39, 41, 43-46, 49, 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 19, 21-22, 40, 42, 48, 50-51, 55 are indefinite over the recitation of "capable of hybridizing" because capability is a latent characteristic and the claims do not set forth the

Art Unit: 1656

criteria by which to determine capability. That is, it is not clear whether the recited set of probes have the potential to hybridize or do in fact do hybridize the recited target nucleic acid which is to be detected. Amendment of the claim to read, for example, "which hybridizes" would obviate this rejection.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10-12, 15-27, 30-38, 40-46, 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelhardt et al. (USPN. 6,221,581) and in view of Pandian et al. (USPN. 5,627,030).

Engelhardt et al. teach a method for detecting a target nucleic acid wherein Engelhardt et al. disclose that the method comprises (i) hybridizing a single-stranded nucleic acid to

Art Unit: 1656

polynucleotide probes (capture probe and labeled probes or signal probes) each single-stranded polynucleotide probe prevents from hybridizing to each other during hybridization and each polynucleotide probe is capable of hybridizing with the same strand of the target genetic material, each can hybridize to a separate sequence of the same strand of target nucleic acid (non overlapping regions) forming a double- hybrid (see column 5, 1-25); (ii) capturing the hybrid to form a bound hybrid with a labeled particle (solid phase such as glass, nylon, polystyrene) and detecting the bound hybrid. (iii) polynucleotide probe can be labeled with a ligand such as biotin and the solid particle is coated with avidin (see column 5, lines 54-67 and column 6, lines 1-12); (iii) double-stranded hybrid can be DNA-RNA hybrid (see column 16, lines 40, 43); (iv) detecting the RNA-DNA hybrid could be done by using antibody which can be labeled with alkaline phosphatase (see column 8, lines 37-65); the method could be used to detect mutations in a target nucleic acid (see column 12, lines 25-610. However, Engelhardt et al. did not teach blocker probe, poly(A)-tail probes and bridge probes.

Pandian et al. teach a method for detecting a target nucleic acid-probe hybrid wherein Pandian et al. disclose the method comprises amplification probe which hybridizes to the probe-target complex (serves as a blocker probe to distinguish from non-hybridized sequences (see column 5, lines 48-56). Further, amplification probe can be with poly (A) tail (see column 6, lines 4-13); the hybrid complex can be hybridized to an amplification probe (bridge probes) with repeat sequences (see column 6, lines 35-58).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting a target nucleic acid as taught by Engelhardt et al. with the method of Pandian et al. which is applicable to detect more complex

Art Unit: 1656

target such as M13 phage because Engelhardt et al. states that 'the method can be carried out by any conventional hybridization assay, by the methods of this invention or by any hybridization assay to be developed in the future. Utilizing such probe provides an easy method for detection of large mutations'. One form of such improvement in developing a hybridization probe, expressly motivated by Pandian et al. is to use a poly (A) tail probe which contains repeat segments to provide a more rapid detection of mutations in a target nucleic acid '. An ordinary practitioner would have been motivated to combine the method of Engelhardt et al. with the method of Pandian et al. in order to achieve the expected advantage of highly sensitive and rapid hybridization method for the detection of a target nucleic acid.

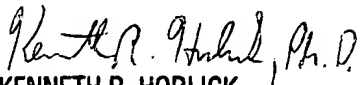
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
October 9, 2001

  
KENNETH R. HORLICK  
PRIMARY EXAMINER  
GROUP 1600  
10/9/01